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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/346,069	07/01/1999	BRUCE A. KEYT	A-/62326-2/R	1979

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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/23/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/346,069

Applicant(s)

KEYT ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 and 18-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 and 18-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is
5 eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/03 has been entered.

Inventorship

10 The request to correct the inventorship of this nonprovisional application under 37 CFR 1.48(a) is deficient because: While both a new Oath/Declaration and a letter of Assignee's Consent was submitted with the inventorship correction request on 2/27/03, 1) it lacks the written consent of any assignee of one of the originally named inventors and 2) the oath or declaration by each actual inventor or inventors listing the entire inventive entity has not been
15 signed by any inventor.

Response to Amendment

The rejection of claims 15 and 18 under 35 USC 112, first paragraph, is withdrawn in view of the amendment to the claims.

20 The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by Tischer et al. (US Patent 5,219,739, reference 11 cited by Applicants) , is withdrawn in view of the amendment to the claims.

The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Tischer et al. (US Patent 5,219,739), is withdrawn in view of the amendment to the claims.

25 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The amendment filed January 15, 2002, remains objected to under 35 U.S.C. 132 because

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it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to page 5, line 4, adding the paragraph with Phe 17, Ile 43 and/or Ile 46. Applicant is required to cancel the new matter in the
5 reply to this Office Action.

Applicant argues that the present application is a CIP of 08/691,794, now US Patent 6,057,418, and incorporated by reference (paper #20, last line of first page of REMARKS), so that there is not new matter introduced by the previously noted amendment. The argument has been fully considered, but is not persuasive. If the parent application was not properly
10 incorporated by reference, as is the case here, matter added *after* the filing of the instant application to the instant application from that parent is new matter. As discussed in the previous Office action for the arguments for the rejection under 35 USC 112, first paragraph (paper #15, middle of page 4):

15 While priority may be amended, if the instant application did not originally (*i.e.*, as filed) incorporate the matter of 08/691,794 by reference, then added subject matter from 08/691,794 constitutes added new matter if it did not originally appear in the instant application or originally claimed priority application 08/567,200 and provisional 60/002,827.

20 Further, according to MPEP 201 (emphasis added by Examiner):

In a continuation or divisional application, the safeguard (petition and fee under former 37CFR 1.60(b)) concerning the filing of an application lacking all of the pages of the specification or sheets of drawings of the prior application has not been retained in 37 CFR 1.53(b) since the specification and drawings of a continuation or divisional
25 application are not limited to a reproduction or a "true copy" of the prior application. As a safeguard, however, an applicant may incorporate by reference the prior application by including, in the continuation or divisional application-as-filed, a statement that such specifically enumerated prior application or applications are "hereby incorporated herein by reference." The statement may appear in the specification or in the application
30 transmittal letter. The incorporation by reference statement can only be relied upon to permit the entering of a portion of the prior application into the continuation or divisional application when the portion of the prior application has been inadvertently omitted from the submitted application papers in the continuation or divisional application. The inclusion of this incorporation by reference of the prior application(s) will permit an
35 applicant to amend the continuation or divisional application to include any subject matter in such prior application(s), without the need for a petition provided the continuation or divisional application is entitled to a filing date notwithstanding the

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incorporation by reference. A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed. *For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim under 35 U.S.C. 120 after the filing date of the application, the amendment would not be proper. When a benefit claim under 35 U.S.C. 120 is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application. See Dart Indus. v. Banner, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980).<*

Double Patenting

Claim 18 remains rejected under the judicially created doctrine of double patenting over claim 1 of U. S. Patent No. 6,057,428 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent, for the reasons set forth in the previous Office action (paper #13, p. 2, line 33- p. 3, line 8).

Claim 15 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,057,428, for the reasons set forth in the previous Office action (paper #15, p. 3, bottom).

Applicant's intention to postpone addressing the rejection until subject matter is indicated as allowable and in the event that claims are amended remains acknowledged.

Claim Rejections - 35 USC § 101

Claims 19-21, 23, 25, 27, 29-32 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter for the reasons set forth in the previous Office action (paper #15, p. 2, bottom).

Applicant argues that the claims are directed to statutory subject matter for reasons of record and claim 18 has been amended to include "non-naturally occurring" [to distinguish from naturally occurring variants (discussed by examiner in previous Office action, paper #15, top of

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page 3)]. The argument has been fully considered, but is not persuasive. The rejection remains over claims 19-21, 23, 25, 27, 29-32, despite the amendment to claim 18. Claim 19 is an independent claim that still reads on naturally occurring variants and does not show the "hand of man". (*N.b.*: The above amendment to claim 18 was sufficient to overcome its rejections over the prior art.)

Claim Rejections - 35 USC § 112, First Paragraph

Claims 19-33 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the previous Office action (paper #15, p. 4, middle). There does not appear to be support in the instant specification for modification of the following amino acids as recited in the newly added claims: Phe 17, Ile 46 and Ile 43.

Applicant argues that the claims find support through reliance on the disclosure of parent application 08/691,794, and that the specification has been amended to include these modifications and provide written description. The argument has been fully considered, but is not persuasive. Applicant has amended the specification and priority of the instant application to claim benefit as a CIP of 08/691,794, which contains the above modifications. Nevertheless, for the reasons of record and as discussed above in the argument to the objection to the specification, the claims contain new matter since the material relied upon in 08/691,794 has not been properly incorporated by reference and does not appear in this application as filed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

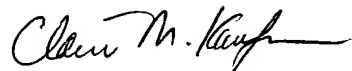
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

April 21, 2003